REMARKS

Status and Disposition of the Claims

Following the Final Office Action dated January 21, 2009, claims 36-62 are pending. Claims 36-43 and 50-62 stand rejected under 35 U.S.C. § 103(a) and claims 44-49 are withdrawn. Claims 36-43 were rejected as being unpatentable over U.S. Patent No. 5,954,739 to Bonutti ("Bonutti") in view of U.S. Patent No. 5,735,865 to Schaumann et al. ("Schaumann"). Claims 50-52, 57, and 58 were rejected as being unpatentable over Bonutti as modified in view of U.S. Patent No. 5,429,139 to Milo et al. ("Milo"). Claims 53-56, 60, and 61 were rejected as being unpatentable over Bonutti as modified in view of U.S. Patent No. 6,602,246 to Sharps et al. ("Sharps"). Claim 59 was rejected as being unpatentable over Bonutti as modified in view of U.S. Patent No. 5,985,320 to Edwards et al. ("Edwards"). Claim 62 was rejected as being unpatentable over Bonutti as modified in view of U.S. Patent No. 6,428,486 to Ritchart et al. ("Ritchart").

By this Amendment, Applicant has canceled claims 36-39, 42, and 60-62, amended claims 40-41, 55, 57, and 59, and added new claims 63-67. No new matter has been added. Claims 40-41, 43, 50-59, and 63-67 are pending for examination.

Rejection of the Claims Under 35 U.S.C. § 103(a)

Claims 36-43 and 50-62 stand rejected under 35 U.S.C. § 103(a). Applicant traverses these rejections. Claims 36-39, 42, and 60-62 have been cancelled, rendering the rejection of these claims moot. Further, Applicant respectfully submits that the § 103(a) rejections of claims 40-41, 43, and 50-59 should be withdrawn,

because the Examiner has not established a *prima facie* case of obviousness as required by M.P.E.P. § 2142 for at least the following reasons.

Claims 40 and 41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bonutti in view of Schaumann. The Examiner alleges that Bonutti discloses each of the elements of the claims except for "a cannula having a side aperture proximal to its distal end, a trocar/needle, a barbed member coaxially received within said cannula and a cutting member/blade/hook received on the cannula." Office Action at p. 3. The Examiner further alleges that Schaumann teaches these missing elements, and that it would have been obvious to one of ordinary skill in the art at the time the invention was made "to combine the insertion member of Bonutti with the cannula with side aperture and respective barbed/cutting/blade and trocar/needle members of Schaumann[.]" *Id.* at p. 4.

Claim 40, as amended, recites "an expandable device sized and shaped to be inserted into the epidural space by the insertion member and configured to be expanded so as to protect and displace a portion of the thecal sac and provide a safety zone within the epidural space." However, nowhere does Bonutti nor Schaumann disclose, teach, or suggest an expandable device sized and shaped to be inserted into the epidural space. Additionally, neither reference, alone or in combination, discloses, teaches, or suggests an expandable device configured to protect and displace a portion of the thecal sac.

Bonutti provides a tissue retractor for spreading a bone joint or dissecting tissue layers. *See* Bonutti, Abstract. Bonutti explicitly states that prior art devices were not "powerful enough" or "made of material which is strong and resilient enough to, for

example, separate tissue planes from within." *Id.* at col. 1, ll. 47-50. Joints and connective tissue require large forces to separate adjacent structures, and traditional inflatable devices "do not have anywhere near the strength, or the ability to hold enough fluid pressure, or shapes to retract tissue as described herein." *Id.* at col. 2, ll. 43-45. To accommodate these greater pressures, the devices of Bonutti are made of Kevlar or Mylar, and may be reinforced with steel, nylon, or other fibers. *Id.* at col. 2, ll. 46-51.

In contrast to Bonutti, the present application is directed to epidural structures, such as, for example, the thecal sac and ligamentum flavum. *See* Current Application, para. 0046, 0047, Figs. 1, 2. Because the thecal sac is mostly water, it is highly compressible. *Id.* at para. 0047. As such, any displacement or compression of the thecal sac should be performed gently. *Id.* at para. 0048. Consequently, "the expandable device is gently expanded via mechanical means or inflated with air or another sterile fluid." *Id.* at para. 0089.

The Examiner alleges that Bonutti discloses "an expandable device (46) adapted to be inserted into the epidural space (col. 3, lines 56-58)...." Office Action at p. 3. Applicant respectfully submits that this is a mischaracterization of the reference.

At column 3, lines 56-60, Bonutti states that an alternate "use for the retractor of the present invention is to operate in a joint of the spine, and specifically between two vertabrae. The retractor is used to spread two vertabrae apart to enable removal of the spinal disc from between the vertabrae." An expandable device sized and shaped to be inserted into the epidural space and configured to be expanded so as to protect and displace a portion of the thecal sac can not be used to spread two vertebrae apart. As stated above by Bonutti, only a retractor that is specifically designed to withstand high

forces and made of sufficiently strong material could be used for such a purpose. Thus, the very purpose of Bonutti can not be achieved with the claimed "expandable device."

Bonutti's retractor cannot be inserted into the epidural space to protect and displace a portion of the thecal sac. On the contrary, Bonutti repeatedly emphasizes that the retractors disclosed are constructed to exert pressures on tissue not previously obtainable, and repeatedly highlights the advantages of such retractors, including the ability of retracting adjacent vertebrae. *See* Bonutti at col. 1, ll. 47-50, col. 2, ll. 39-54, col. 9, ll. 5-7. Consequently, Bonutti fails to disclose, teach, or suggest "an expandable device sized and shaped to be inserted into the epidural space by the insertion member and configured to be expanded so as to protect and displace a portion of the thecal sac and provide a safety zone within the epidural space." Moreover, the Examiner has not provided a tenable rationale explaining why or how one of ordinary skill in the art would modify Bonutti's device in an attempt to arrive at the claimed invention. Such an explanation is particularly necessary given that Bonutti's device is designed to exert high pressures that would be unsuitable for use in the epidural space.

Furthermore, Schaumann fails to cure the deficiencies of Bonutti. Claim 40 has been amended to recite, "an insertion member for accessing the epidural space, the insertion member comprising a tissue piercing distal tip[.]" The Examiner relies on Schaumann's disclosure for the teaching of a tubular shank instrument. However, the tubular instrument shank 1 taught by Schaumann "is atraumatically rounded at its distal end[.]" *Id.* at col. 3, ll. 36-37. Thus, Schaumann fails to disclose an insertion member comprising a tissue piercing distal tip.

Moreover, modifying the shank taught by Schaumann to include a tissue piercing distal tip would not have been obvious to one of ordinary skill in the art. Schaumann states that an object of the invention is to improve an instrument for treating "carpal tunnel syndrome, such that an inadvertent cutting of tissue on introduction of the instrument or on diagnosis is avoided[.]" Schaumann at col. 2, ll. 42-44. However, modifying the shank taught by Schaumann to include a tissue piercing distal tip would greatly increase the likelihood of inadvertently cutting tissue, rendering the instrument unsatisfactory for its intended purpose. The M.P.E.P. instructs that "[i]f [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." M.P.E.P. § 2143.01 (citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)). Therefore, Schaumann fails to disclose, teach, or suggest the claimed insertion member that includes a tissue piercing distal tip.

For at least the foregoing reasons, Applicant submits that the references, alone or in combination, fail to disclose, teach, or suggest each and every limitation of claim 40. Applicant therefore submits that the §103(a) rejections of claim 40 should be withdrawn. Additionally, claims 41, 43, and 50-59, as amended, all depend from claim 40, and it is therefore respectfully submitted that these claims are allowable for at least the same reasons as claim 40.

New Claims

Newly added claims 63-67 depend from amended claim 40. It is respectfully submitted that these claims distinguish over the prior art of record and are allowable for at least the same reasons as independent claim 40. No new matter has been added.

Conclusion

The Office Action contains characterizations of the claims and the related art with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Office Action.

In discussing the claims in this Amendment, it is to be understood that Applicant is in no way intending to limit the scope of the claims to any exemplary embodiments described in the specification, abstract, or shown in the drawings. Rather, Applicant is entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

Applicant respectfully requests that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 40-41, 43, 50-59, and 63-67 in condition for allowance. Applicant submits that the proposed amendments of claims 40-41, 55, 57, and 59 do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Furthermore, Applicant respectfully points out that the final action by the Examiner presented some new arguments as to the application of the art against Applicant's invention. It is respectfully submitted that the entering of the Amendment would allow the Applicant to reply to the final rejections and place the application in condition for allowance.

Finally, Applicant submits that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicant submits that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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